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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/514,070	02/26/2000	Merrill A Biel	22272-14	8621

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EXAMINER	
SHAY, DAVID M	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 03/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/514,070	BIEL, MERRILL A	
	Examiner	Art Unit	
	david shay	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *July 27, 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-53 and 55-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-53 and 55-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *July 27, 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant argues that "Lai et al does not teach or suggest the use of SDS, at any concentration, for an in vivo application." (emphasis in original). The examiner respectfully notes that since Singer et al teach he use of SDS for in vivo applications, it is not necessary for Lai et al to provide the teaching as well. Applicant then argues that the combination of Lai et al and Singer et al do not teach each of the steps of claim 53. Lai et al clearly teach the application of a photosensitizer to an area of cell activity, and exposing, photosensitive material to light (see column 1, line 12-27). Singer et al teach that the effects of SDS at concentrations below the critical micell concentration (CMC) which includes the range 0.003-0.01%, noting that "the main target structure is the cell membrane" and "at concentrations below CMC, membranes lose their barrier capacity, greatly increasing permeability" (emphasis added). Singer et al also note the use of SDS as a delivery aid for pharmaceuticals. Clearly this is a motivation to employ the SDS concentration in the method of Lai et al, thus applicant's reliance on *Royka* is misplaced. Further the inclusion of SDS in the method of Lai et al will inherently disorient the cell membrane and similarly the photosensitizer of Lai et al will pass there through. As the disorienting and passing are inherent in the use of SDS, it is not necessary that either reference recognize or rely on the effect, the steps still occur, as already set forth in the previous rejection. Regarding the particular concentration applicant claims, Singer et al specifically states that the behavior of SDS is well known and its surfactant properties have been studied extensively (see page 96, second full paragraph) and that the effects are generally linear with a respect to concentration below the CMC (see page 101).

Applicant argues that there is no motivation to combine Swartz and Singer et al. Applicant alleges, proffering Gyenge et al as a basis, that the use of SDS would inhibit the

formation of hydrogen peroxide. Applicant describes the subject of the Gyenge et al article as "an analogous system" to that of Swartz. The examiner must respectfully disagree. The micro ampere range of current used by Swartz (see figure 4) is in no way analogous to the hundreds of amperes used by Gyenge et al (see the first sentence of the paragraph bridging pages 234 and 235) as noted by Gyenge et al the context of the production of peroxide is that of blanching wood pulp in the presence of relatively high concentrations of Sulfuric acid or Sodium hydroxide (the active ingredient in Drano™). These conditions are in no way analogous to and are in fact quite inimical to the treatment of e.g. mucus tissue, as taught by Swartz. As the systems of Gyenge and Swartz are clearly non-analogous, applicant's arguments, predicated on the analogousness thereof are not convincing.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai et al combination with Singer et al. Lai et al teach a method of cellular disruption using a photosensitizing agent (column 6, line 36 to column 19, lines 67). Singer et al teach that at concentrations of SDS below that at which complete cell lysis occurs, cell permeability is greatly increased and that SDS is used as a delivery aid in pharmaceuticals. It would have been obvious to the artisan of ordinary skill to employ SDS in the method of Lai et al, since this would aid the delivery of the pharmaceutical agent and to employ an SDS concentration as claimed, since this is merely a matter of design choice and since Singer et al give no minimum concentration below which the "cell permeability is greatly increased" as this happens at any concentration below that

at which cell lysis occurs, as taught by Singer et al, and since this would reduce the extent to which non-cancerous cells are affected.

Claims 50-53, 55, and 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz et al in combination with Asculai et al, Singer et al, and Williams et al. Swartz et al teaches a method such as claimed except the se of a surfactant (please note the absence of teaching of the use of a surfactant necessary includes the absence of limitations predicated on the use of surfactant e.g. the use of a particular concentration of surfactant) and gives few particulars regarding light application. Asculai et al teach the usefulness of surfactants for inactivating viruses. Singer et al teach that SDS permiabilizes membranes greatly at concentrations below that at which total lysis occurs. Williams et al teach controlling gel properties through the use of surfactants. It would have been obvious to the artisan of ordinary skill to employ a surfactant in the method of Swartz et al since this would help inactivate the virus, as taught by Asculai et al as well as to control gel properties, as taught by Williams et al; and to use the claimed concentrations, since this is merely a matter of design choice and these will permiabilized the membranes by attacking the lipids therein, as taught by Singer et al, thus producing a method such as claimed.

Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz et al in combination with Asculai et al, and Williams et al as applied to claims 50-53, 55 and 57-59 above, and further in combination with Lai et al. Lai et al teach light dosages and dosage rates as claimed for activating a photosensitizer. It would have been obvious to the artisan of ordinary skill to employ the dosage and dosage rate as taught by Lai et al, since these will activate the

photosensitizer and since Swartz et al supply no particular dosage or dosage rates, thus producing a method such as claimed.

Applicant's arguments filed July 27, 2004 have been fully considered but they are not persuasive. The arguments are not convincing for the revenue set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to David Shay at telephone number (571) 272-4773.

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330